

1 What is claimed is:

2

3 1. In a stented graft that can alternately include a compact configuration having  
4 a first diameter and an expanded configuration having a greater diameter,  
5 comprising, in combination:

6 ☐ at least one stent formed in a generally cylindrical shape having an  
7 outer surface and a hollow bore extending longitudinally therethrough,  
8 wherein said stent can alternately exist in a compact configuration  
9 having a first diameter, and an expanded configuration having a  
10 greater diameter and a plurality of lateral openings; and,

11 ☐ a flexible, porous, biocompatible tubular elastomer covering having a  
12 first end, a second end, an outer surface and a hollow bore that  
13 extends longitudinally therethrough to define an inner surface;

14 said stent being deployed coaxially within said hollow bore of said covering  
15 such that said inner surface of said tubular covering is in contact with said  
16 outer surface of said stent;

17 the improvement wherein said stent comprises a plurality of elements,  
18 wherein each said element comprises an undulating linear shape formed  
19 into a generally cylindrical configuration having a cylinder axis generally  
20 aligned on the axis of said hollow bore, and wherein each said element is  
21 connected to an adjacent neighbor element by at least one linear connector.

22

- 1 2. The stented graft of claim 1, wherein said plurality of elements comprises a  
2 spiral.  
3
- 4 3. The stented graft of claim 1, wherein at least one said connector is  
5 substantially circumferentially offset from an adjacent neighbor connector.  
6
- 7 4. The stented graft of claim 3, wherein said circumferentially offset connectors  
8 form a helical array.  
9
- 10 5. The stented graft of claim 1, wherein at least one said connector is not  
11 substantially circumferentially offset from an adjacent neighbor connector.  
12
- 13 6. The stented graft of claim 1, wherein said undulating linear shape is a  
14 generally zigzag shape comprising a plurality of zigs having tips and a  
15 plurality of zags having tips, wherein said tip of each said zig of each element  
16 and the nearest said tip of each said zig of an adjacent neighbor element  
17 generally lie in a plane passing through the axis of said hollow bore, and  
18 wherein said tip of at least one said zig of each element and at least one said  
19 nearest said tip of a zig of an adjacent neighbor are connected by one said  
20 linear connector.  
21
- 22 7. The stented graft of claim 1, wherein said undulating linear shape is a  
23 sinusoidal shape having a plurality of peaks and a plurality of valleys, wherein

1 each said peak of each element and each said valley of an adjacent neighbor  
2 lie generally in a common plane passing through the axis of said hollow bore,  
3 and wherein at least one said peak of each element and said valley of an  
4 adjacent neighbor lying generally in said common plane are connected by  
5 one said linear connector.

6  
7 8. The stented graft of claim 1, wherein each said linear connector has a length  
8 dimension generally parallel to the axis of said hollow bore, and a width and  
9 depth dimension, and wherein said length dimension is greater than said  
10 width dimension and said length dimension is greater than said depth  
11 dimension.

12  
13 9. The stented graft of claim 8, wherein said length dimension is about 3 to 10  
14 times greater than said width dimension, and said length dimension is about 3  
15 to 10 times greater than said depth dimension.

16  
17 10. The stented graft according to claim 1, wherein said stent and said elastomer  
18 are anchored to each other by means for anchoring.

19  
20 11. The tubular stented graft according to claim 10, wherein said means for  
21 anchoring comprise protrusions of said covering that fixedly protrude into said  
22 lateral openings in said stent.

23

12. The stented graft of claim 1 wherein said elastomer covering is formed of an elastomer selected from the group consisting of polytetrafluoroethylene, fluorinated ethylene propylene, polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer, polyvinyl chloride, polypropylene, polyethylene terephthalate, broad fluoride; and, other biocompatible plastics.

13. The stented graft of claim 1 wherein said elastomer covering is formed of expanded, sintered PTFE tape, said tape having been wound about the outer surface of said stent to create said covering thereon.

14. The stented graft of claim 12, wherein said polytetrafluoroethylene is expanded polytetrafluoroethylene having fibrils.

15. The stented graft of claim 14, wherein said fibrils measure up to about 300  $\mu$  in length.

16. The stented graft of claim 14, wherein said fibrils measure up to about 200  $\mu$  in length.

17. The stented graft of claim 14, wherein said fibrils measure up to about 100  $\mu$  in length.

1 18. The stented graft of claim 14, wherein said fibrils measure up to about 50  $\mu$  in  
2 length.

3  
4 19. The stented graft of claim 14, wherein said fibrils measure up to about 5  $\mu$  in  
5 length.

6  
7 20. The stented graft of claim 13 wherein said tape has a width of less than about  
8 1 inch.

9  
10 21. The stented graft of claim 13 wherein said tape has a thickness of less than  
11 0.015 inch (0.038 cm.) and wherein said tape is wound about said stent in  
12 overlapping fashion, such that said elastomer covering comprises 1 to 10  
13 layers of said tape.

14  
15 22. The stented graft of claim 13 wherein said tape is helically wrapped about  
16 said stent.

17  
18 23. The stented graft of claim 13 wherein said tape has a width of 0.5 inches  
19 (1.27 cm), and wherein said tape is helically wrapped such that 6-8  
20 revolutions of tape are applied per longitudinal inch (2.54 cm.) of said stented  
21 graft.

22

24. The stented graft of claim 13 wherein said tape is helically wrapped alternately in a first direction and then in the opposite direction.

25. The stented graft of claim 24 further comprising 8 layers of said tape.

26. The stented graft of claim 1 wherein said stent is a self-expanding stent.

27. The stented graft of claim 26, wherein said self-expanding stent comprises a shape memory alloy that can alternately exist in a first and a second crystalline state, wherein said stent assumes a radially expanded configuration when said shape memory alloy is in said first crystalline state, and a radially compact configuration when said shape memory alloy is in said second crystalline state.

28. The stented graft of claim 1 wherein said stent is a pressure-expandable stent.

29. The stented graft of claim 1 wherein said stent is formed of a metal alloy comprising at least two elements selected from the group consisting of iron, cobalt, chromium, nickel, titanium, niobium, and molybdenum.

30. The stented graft of claim 27 wherein said shape memory alloy comprises at least about 51% to about 59% nickel and the remainder comprising titanium.

1

2 31. The stented graft of claim 27 wherein said shape memory alloy comprises  
3 about 0.25% chromium, at least about 51% to about 59% nickel, and the  
4 remainder comprising titanium.

5

6 32. The stented graft of claim 1 wherein said covering has a thickness of less  
7 than 0.1 inch (0.25 cm.).

8

9 33. The stented graft of claim 13 wherein said PTFE tape has a thickness of less  
10 than 0.015 inches (0.038 cm.), said tape being wrapped about said stent in  
11 overlapping fashion so as to form said covering.

12

13 34. The stented graft of claim 13 wherein said PTFE tape has a density of less  
14 than 1.6 g/cc.

15

16 35. The stented graft of claim 13 wherein said covering has a thickness of less  
17 than 0.1 inch (0.25 cm.) and said PTFE tape has a density of less than 1.6  
18 g/cc.

19

20 36. The stented graft of claim 1 wherein said stent further comprises a polymer  
21 coating formed on said stent.

22

1 37. The stented graft of claim 36 wherein said polymer coating formed on said  
2 stent is of a polymer material selected from the group consisting of  
3 polytetrafluoroethylene, fluorinated ethylene propylene,  
4 polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer, polyvinyl  
5 chloride, polypropylene, polyethylene terephthalate, polyvinylidene fluoride,  
6 and, other biocompatible plastics.

7  
8 38. The stented graft of claim 36 wherein said polymer coating was  
9 applied to said stent by the steps of:

- 10 ☐ immersing said stent in a liquid polymer dispersion;  
11 ☐ removing said stent from said liquid polymer dispersion; and,  
12 ☐ drying said liquid polymer dispersion that has remained on said stent,  
13 whereby said polymer coating is formed on said stent.

14  
15 39. The stented graft of claim 36 wherein said polymer coating is formed by  
16 electron beam deposition.

17  
18 40. The stented graft of claim 36 wherein said tubular covering is adherent to said  
19 polymer coating.

20  
21 41. A method for the treatment of cardiovascular disease, comprising implanting  
22 the stented graft of claim 1 in a patient in need of such treatment wherein said



1        implantation is effective to ameliorate one or more of the symptoms of said  
2        cardiovascular disease.

3  
4        42. An article of manufacture, comprising packaging material and the stented  
5        graft of claim 1 contained within the packaging material, wherein said stented  
6        graft is effective for implantation in a patient afflicted with cardiovascular  
7        disease, and the packaging material includes a label that indicates that said  
8        device is effective for said implantation.

9  
10       43. In a stented graft that can alternately include a compact configuration having  
11       a first diameter and an expanded configuration having a greater diameter,  
12       comprising, in combination:

- 13       □ at least one stent formed in a generally cylindrical shape having an  
14       outer surface and a hollow bore extending longitudinally therethrough  
15       to form an inner surface, wherein said stent can alternately exist in a  
16       compact configuration having a first diameter, and an expanded  
17       configuration having a greater diameter and a plurality of lateral  
18       openings; and,  
19       □ a tubular inner graft formed of an elastomer, said tubular inner graft  
20       having an outer surface and an inner surface, said tubular inner graft  
21       being deployed coaxially within said hollow bore of said stent; whereby  
22       said outer surface of said tubular inner graft is in contact with said  
23       inner surface of said stent;

1 the improvement wherein said stent comprises a plurality of elements,  
2 wherein each said element comprises an undulating linear shape formed into  
3 a generally cylindrical configuration having a cylinder axis generally aligned  
4 on the axis of said hollow bore, and wherein each said element is connected  
5 to an adjacent neighbor element by at least one linear connector.

6  
7 44. The stented graft of claim 43, wherein said plurality of elements comprises a  
8 spiral.

9  
10 45. The stented graft of claim 43, wherein at least one said connector is  
11 substantially circumferentially offset from an adjacent neighbor connector.

12  
13 46. The stented graft of claim 45, wherein said circumferentially offset connectors  
14 form a helical array.

15  
16 47. The stented graft of claim 43, wherein at least one said connector is not  
17 substantially circumferentially offset from an adjacent neighbor connector.

18  
19 48. The stented graft of claim 43, wherein said undulating linear shape is a  
20 generally zigzag shape comprising a plurality of zigs having tips and a  
21 plurality of zags having tips, wherein said tip of each said zig of each element  
22 and the nearest said tip of each said zig of an adjacent neighbor element  
23 generally lie in a plane passing through the axis of said hollow bore, and

1 wherein said tip of at least one said zig of each element and at least one said  
2 nearest said tip of a zig of an adjacent neighbor are connected by one said  
3 linear connector.  
4

5 49. The stented graft of claim 43, wherein said undulating linear shape is a  
6 sinusoidal shape having a plurality of peaks and a plurality of valleys, wherein  
7 each said peak of each element and each said valley of an adjacent neighbor  
8 lie generally in a common plane passing through the axis of said hollow bore,  
9 and wherein at least one said peak of each element and said valley of an  
10 adjacent neighbor lying generally in said plane are connected by one said  
11 linear connector.  
12

13 50. The stented graft of claim 43, wherein each said linear connector has a length  
14 dimension generally parallel to the axis of said hollow bore, and a width and  
15 depth dimension, and wherein said length dimension is greater than said  
16 width dimension and said length dimension is greater than said depth  
17 dimension.  
18

19 51. The stented graft of claim 50, wherein said length dimension is about 3 to 10  
20 times greater than said width dimension, and said length dimension is about 3  
21 to 10 times greater than said depth dimension.  
22

52. The stented graft according to claim 43, wherein said stent and said elastomer are anchored to each other by means for anchoring.

53. The stented graft according to claim 43, wherein said means for anchoring comprise protrusions of said outer surface that fixedly protrude into said lateral openings in said stent.

54. The stented graft of claim 43 wherein said elastomer is selected from the group consisting of polytetrafluoroethylene, fluorinated ethylene propylene, polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer, polyvinyl chloride, polypropylene, polyethylene terephthalate, broad fluoride; and, other biocompatible plastics.

55. The stented graft of claim 54, wherein said polytetrafluoroethylene is expanded polytetrafluoroethylene having fibrils.

56. The stented graft of claim 55, wherein said fibrils measure up to about 300  $\mu$  in length.

57. The stented graft of claim 55, wherein said fibrils measure up to about 200  $\mu$  in length.

1 58. The stented graft of claim 55, wherein said fibrils measure up to about 100  $\mu$   
2 in length.

3  
4 59. The stented graft of claim 55, wherein said fibrils measure up to about 50  $\mu$  in  
5 length.

6  
7 60. The stented graft of claim 55, wherein said fibrils measure up to about 5  $\mu$  in  
8 length.

9  
10 61. The stented graft of claim 43 wherein said stent is a self-expanding stent.

11  
12 62. The stented graft of claim 61, wherein said self-expanding stent comprises a  
13 shape memory alloy that can alternately exist in a first and a second  
14 crystalline state, wherein said stent assumes a radially expanded  
15 configuration when said shape memory alloy is in said first crystalline state,  
16 and a radially compact configuration when said shape memory alloy is in said  
17 second crystalline state.

18  
19 63. The stented graft of claim 43 wherein said stent is a pressure-expandable  
20 stent.

21

64. The stented graft of claim 43 wherein said stent is formed of a metal alloy comprising at least two elements selected from the group consisting of iron, cobalt, chromium, nickel, titanium, niobium, and molybdenum.

65. The stented graft of claim 62 wherein said shape memory alloy comprises at least about 51% to about 59% nickel and the remainder comprising titanium.

66. The stented graft of claim 62 wherein said shape memory alloy comprises about 0.25% chromium, at least about 51% to about 59% nickel, and the remainder comprising titanium.

67. The stented graft of claim 43 wherein said stent further comprises a polymer coating formed on said stent.

68. The stented graft of claim 67 wherein the polymer coating formed on said stent is of a polymer material selected from the group consisting of polytetrafluoroethylene, fluorinated ethylene propylene, polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer, polyvinyl chloride, polypropylene, polyethylene terephthalate, polyvinylidene fluoride, and, other biocompatible plastics.

69. The stented graft of claim 67 wherein said polymer coating was applied to said stent by the steps of:

- immersing said stent in a liquid polymer dispersion;
  - removing said stent from said liquid polymer dispersion; and,
  - drying said liquid polymer dispersion that has remained on said stent,
- whereby said polymer coating is formed on said stent.

70. The stented graft of claim 67 wherein said polymer coating is formed by electron beam deposition.

71. The stented graft of claim 43 wherein said elastomer is adherent to said polymer coating.

72. A method for the treatment of cardiovascular disease, comprising implanting the stented graft of claim 43 in a patient in need of such treatment wherein said implantation is effective to ameliorate one or more of the symptoms of said cardiovascular disease.

73. An article of manufacture, comprising packaging material and the stented graft of claim 43 contained within the packaging material, wherein said stented graft is effective for implantation in a patient afflicted with cardiovascular disease, and the packaging material includes a label that indicates that said device is effective for said implantation.

1 74. An improved tubular stented graft which is alternately deployable in a radially  
2 compact configuration having a first diameter and a radially expanded  
3 configuration having a second diameter, said stented graft comprising:

4 • a stent comprising:

5 □ at least one member formed in a generally cylindrical shape having  
6 an outer surface and a hollow bore which extends longitudinally  
7 therethrough to define an inner surface;

8 □ said stent being initially radially collapsible to a diameter which is  
9 substantially equal to said first diameter of the stented graft, and  
10 subsequently radially expandable to a diameter which is  
11 substantially equal to said second diameter of the stented graft;  
12 and,

13 □ a plurality of lateral openings existing in said stent when said stent is at  
14 its radially expanded second diameter;

15 • a continuous, tubular PTFE covering formed on said stent, said PTFE  
16 covering comprising:

17 □ a tubular inner base graft formed of expanded, sintered PTFE, said  
18 tubular base graft having an outer surface and an inner surface, said  
19 tubular base graft being deployed coaxially within the hollow bore of  
20 said stent such that the outer surface of the tubular base graft is in  
21 contact with the inner surface of the stent, and the inner surface of said  
22 tubular base graft thereby defining a luminal passageway through the  
23 stented graft; and,



1       □ a tubular outer layer formed of expanded, sintered PTFE tape which  
2       has a width of less than about 1 inch, said tape having been wound  
3       about the outer surface of said stent to create said tubular outer layer  
4       thereon, such that said stent is captured between said outer layer and  
5       said tubular base graft;  
6       said tubular outer layer being attached to said tubular base graft, through  
7       said lateral openings in said stent, to thereby form an integrally stented,  
8       continuous PTFE tube which is alternately disposable in said radially  
9       compact configuration of said first diameter and said radially expanded  
10      configuration of said second diameter;  
11      the improvement wherein said stent comprises a plurality of elements,  
12      wherein each said element comprises an undulating linear shape formed  
13      into a generally cylindrical configuration having a cylinder axis generally  
14      aligned on the axis of said hollow bore, and wherein each said element is  
15      connected to an adjacent neighbor element by at least one linear  
16      connector.

17  
18   75. The stented graft of claim 74, wherein said plurality of elements comprises a  
19   spiral.

20  
21   76. The stented graft of claim 74, wherein at least one said connector is  
22   substantially circumferentially offset from an adjacent neighbor connector.

23

1 77. The stented graft of claim 76, wherein said circumferentially offset connectors  
2 form a helical array.  
3

4 78. The stented graft of claim 74, wherein at least one said connector is not  
5 substantially circumferentially offset from an adjacent neighbor connector.  
6

7 79. The stented graft of claim 74, wherein said undulating linear shape is a  
8 generally zigzag shape comprising a plurality of zigs having tips and a  
9 plurality of zags having tips, wherein said tip of each said zig of each element  
10 and the nearest said tip of each said zig of an adjacent neighbor element  
11 generally lie in a plane passing through the axis of said hollow bore, and  
12 wherein said tip of at least one said zig of each element and at least one said  
13 nearest said tip of a zig of an adjacent neighbor are connected by one said  
14 linear connector.  
15

16 80. The stented graft of claim 74, wherein said undulating linear shape is a  
17 sinusoidal shape having a plurality of peaks and a plurality of valleys, wherein  
18 each said peak of each element and each said valley of an adjacent neighbor  
19 generally lie in a plane passing through the axis of said hollow bore, and  
20 wherein at least one said peak of each element and said valley of an adjacent  
21 neighbor lying generally in said plane are connected by one said linear  
22 connector.  
23

1 81. The stented graft of claim 74, wherein each said linear connector has a length  
2 dimension generally parallel to the axis of said hollow bore, and a width and  
3 depth dimension, and wherein said length dimension is greater than said  
4 width dimension and said length dimension is greater than said depth  
5 dimension.

6  
7 82. The stented graft of claim 81, wherein said length dimension is about 3 to 10  
8 times greater than said width dimension, and said length dimension is about 3  
9 to 10 times greater than said depth dimension.

10  
11 83. The stented graft of claim 74 wherein said PTFE is replaced by an elastomer  
12 selected from the group consisting of fluorinated ethylene propylene,  
13 polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer, polyvinyl  
14 chloride, polypropylene, polyethylene terephthalate, broad fluoride; and, other  
15 biocompatible plastics.

16  
17 84. The stented graft of claim 74 wherein said PTFE covering is formed of  
18 expanded, sintered PTFE tape, said tape having been wound about the outer  
19 surface of said stent to create said covering thereon.

20  
21 85. The stented graft of claim 74, wherein said PTFE is expanded  
22 polytetrafluoroethylene having fibrils.

23

1 86. The stented graft of claim 85, wherein said fibrils measure up to about 300  $\mu$   
2 in length.

3

4 87. The stented graft of claim 85, wherein said fibrils measure up to about 200  $\mu$   
5 in length.

6

7 88. The stented graft of claim 85, wherein said fibrils measure up to about 100  $\mu$   
8 in length.

9

10 89. The stented graft of claim 85, wherein said fibrils measure up to about 50  $\mu$  in  
11 length.

12

13 90. The stented graft of claim 85, wherein said fibrils measure up to about 5  $\mu$  in  
14 length.

15

16 91. The stented graft of claim 84 wherein said tape has a width of less than about  
17 1 inch (2.54 cm.).

18

19 92. The stented graft of claim 84 wherein said tape has a thickness of less than  
20 0.015 inch (0.038 cm.) and wherein said tape is wound about said stent in  
21 overlapping fashion, such that said elastomer covering comprises 1 to 10  
22 layers of said tape.

23

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1 93. The stented graft of claim 84 wherein said tape is helically wrapped about  
2 said stent.

3  
4 94. The stented graft of claim 84 wherein said tape has a width of 0.5 inches  
5 (1.27 cm), and wherein said tape is helically wrapped such that 6-8  
6 revolutions of tape are applied per longitudinal inch (2.54 cm.) of said stented  
7 graft.

8  
9 95. The stented graft of claim 84 wherein said tape is helically wrapped  
10 alternately in a first direction and then in the opposite direction.

11  
12 96. The stented graft of claim 95 further comprising 8 layers of said tape.

13  
14 97. The stented graft of claim 74 wherein said stent is a self-expanding stent.

15  
16 98. The stented graft of claim 97, wherein said self-expanding stent comprises a  
17 shape memory alloy that can alternately exist in a first and a second  
18 crystalline state, wherein said stent assumes a radially expanded  
19 configuration when said shape memory alloy is in said first crystalline state,  
20 and a radially compact configuration when said shape memory alloy is in said  
21 second crystalline state.

22

1 99. The stented graft of claim 74 wherein said stent is a pressure-expandable  
2 stent.

3  
4 100. The stented graft of claim 97 wherein said stent is formed of a metal alloy  
5 comprising at least two elements selected from the group consisting of iron,  
6 cobalt, chromium, nickel, titanium, niobium, and molybdenum.

7  
8 101. The stented graft of claim 98 wherein said shape memory alloy comprises  
9 at least about 51% to about 59% nickel and the remainder comprising  
10 titanium.

11  
12 102. The stented graft of claim 98 wherein said shape memory alloy comprises  
13 about 0.25% chromium, at least about 51% to about 59% nickel, and the  
14 remainder comprising titanium.

15  
16 103. The stented graft of claim 74 wherein said covering has a thickness of less  
17 than 0.1 inch (0.25 cm.).

18  
19 104. The stented graft of claim 84 wherein said PTFE tape has a thickness of  
20 less than 0.015 inches (0.038 cm.), said tape being wrapped about said stent  
21 in overlapping fashion so as to form said covering.

22

1 105. The stented graft of claim 84 wherein said PTFE tape has a density of less  
2 than 1.6 g/cc.

3  
4 106. The stented graft of claim 84 wherein said covering has a thickness of less  
5 than 0.1 inch (0.25 cm.) and the PTFE tape has a density of less than 1.6  
6 g/cc.

7  
8 107. The stented graft of claim 74 wherein said stent further comprises a  
9 polymer coating formed on said stent.

10  
11 108. The stented graft of claim 107 wherein said polymer coating formed on  
12 said stent is of a polymer material selected from the group consisting of  
13 polytetrafluoroethylene, fluorinated ethylene propylene,  
14 polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer, polyvinyl  
15 chloride, polypropylene, polyethylene terephthalate, polyvinylidene fluoride,  
16 and, other biocompatible plastics.

17  
18 109. The stented graft of claim 107 wherein said polymer coating was  
19 applied to said stent by the steps of:

20 ☐ immersing said stent in a liquid polymer dispersion;  
21 ☐ removing said stent from said liquid polymer dispersion; and,  
22 ☐ drying said liquid polymer dispersion that has remained on said stent,  
23 whereby said polymer coating is formed on said stent.

1

2 110. The stented graft of claim 107 wherein said polymer coating is formed by  
3 electron beam deposition.

4

5 111. The stented graft of claim 107 wherein said tubular covering is adherent to  
6 said polymer coating.

7

8 112. A method for the treatment of cardiovascular disease, comprising  
9 implanting the stented graft of claim 74 in a patient in need of such treatment  
10 wherein said implantation is effective to ameliorate one or more of the  
11 symptoms of said cardiovascular disease.

12

13 113. An article of manufacture, comprising packaging material and the stented  
14 graft of claim 74 contained within the packaging material, wherein said  
15 stented graft is effective for implantation in a patient afflicted with  
16 cardiovascular disease, and the packaging material includes a label that  
17 indicates that said device is effective for said implantation.

18

FOOTNOTES